

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

Y-TRAP, INC.,

Plaintiff,

v.

BIOCON, LTD and BICARA  
THERAPEUTICS, INC.,

Defendants.

Case No. 1:24-cv-12678-GAO

**ORAL ARGUMENT REQUESTED**

**PENDING MOTION FOR LEAVE TO  
FILE EXCESS PAGES (ECF No. 41)  
FILED ON 1/9/2025**

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT BICARA  
THERAPEUTICS, INC.'S MOTION TO DISMISS THE COMPLAINT**

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### **PRELIMINARY STATEMENT**

According to the Complaint, fourteen years ago, Dr. Atul Bedi and Dr. Rajani Rani allegedly invented a specific fusion protein technology, assigned the intellectual property rights to those proteins to non-party Johns Hopkins University (“JHU”), and then shared details concerning that invention with Biocon Limited (“Biocon”), the key partner in an ongoing collaboration with Bedi and Rani. The parties went their separate ways, with Bedi and Rani pursuing certain “Bedi” patents in the intervening years. Later, Bedi and Rani formed plaintiff Y-Trap, Inc. (“Y-Trap”), who purports to be the licensee, through non-party JHU, of the “Bedi” patents. On the other side, Biocon pursued its own inventions, obtaining patents involving fusion proteins in 2014, 2016, 2017, 2018, and beyond. In 2018, Biocon founded then-subsidiary Bicara Therapeutics, Inc. (“Bicara”) to begin studying the lead drug candidate out of that research, ficerafusp alfa (pronounced “fie-sera-fusp” or “fie-sera”), in clinical trials, with Bicara obtaining a license to the patents Biocon had obtained. By 2023, Bicara had outside investors and was spun out from Biocon, though Biocon was still an investor. During all this time, neither Bedi, Rani, Y-Trap, nor JHU (the assignee of the “Bedi” patents) did anything to challenge Bicara’s actions or fusion protein research. Then, in September 2024, Bicara held its initial public offering, raising \$362 million. This lawsuit filed by Y-Trap alone followed one month later.

Y-Trap does not bring claims against Bicara for theft of trade secrets, patent infringement, tortious interference, or the like. Instead, Y-Trap supposes that its founders “should” have been the inventors of the patents Biocon obtained beginning upwards of a decade ago, and so, somehow, it is wrongful under Chapter 93A, as well as common law civil conspiracy and unjust enrichment, for Bicara to have obtained a license to the patents Biocon holds, to pursue development of an antitumor drug candidate claimed in those patents, and to raise money directed at those efforts.

But Y-Trap’s jealousy over Bicara’s successes after more than a decade is not the proper

basis for a suit. Y-Trap's claims against Bicara should be dismissed for three distinct reasons.<sup>1</sup>

*First*, all three of Y-Trap's claims against Bicara are barred by the relevant statutes of limitations. Even as pleaded in the Complaint, the facts purportedly giving rise to Y-Trap's claims have been public record since at least August 2014, when the USPTO began issuing patents to Biocon for the intellectual property at issue (with a total of *six* patents being granted outside any limitations period). Indeed, the very "'789 Bedi IP" patents Y-Trap claims to have license to *cite* Biocon's patents as a reference. What's more, Bicara's clinical trial of ficerafusp alfa, Bicara's drug candidate, has been publicly posted with the National Institutes of Health (on ClinicalTrials.gov) since June 2020, also outside every limitations period. Finally, Y-Trap's Complaint *attaches* a Bicara press release from March 2021 (outside the limitations period for two of its claims) announcing to the world Bicara's development of ficerafusp alfa in partnership with Biocon. Based on the facts as pleaded, any claim for relief is well outside the statute of limitations.

*Second*, Y-Trap fails to plead the required elements of each of the claims it raises against Bicara. Y-Trap fails to plead a claim under Chapter 93A because it does not allege that there was any underlying commercial transaction, any unfair or deceptive trade practice by Bicara, any loss of money or property by Y-Trap, or causation. Y-Trap fails to plead unjust enrichment because it does not allege that Y-Trap conferred any benefit to Bicara, let alone an unjust one. Finally, Y-Trap fails to plead civil conspiracy, and specifically fails to allege either any coercive effect of any supposed conspiracy or any predicate tort.

*Third*, to the extent Y-Trap were to have any claim based on the facts alleged in the

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<sup>1</sup> As required at this stage of litigation, and only for the purposes of this motion, Bicara takes the properly pleaded factual allegations in the Complaint as true. But, Bicara strongly contests the claims made in the Complaint and, should this litigation continue, intends to prove that Y-Trap is not entitled to any relief on the facts, as well as the law.

Complaint, that claim is preempted by federal patent law. The gist of Y-Trap’s allegations is that it is wrong for Bicara to make and use ficerafusp alfa due to Y-Trap’s patent rights. That claim sounds, if at all, as one for patent infringement. And here, there is direct conflict preemption over such a claim—Bicara’s research and development of a drug candidate is expressly shielded by 35 U.S.C. § 271(e)(1). To the extent Y-Trap is seeking to use state law to circumvent Congress’s clear protection of Bicara’s actions, that claim is preempted and should be dismissed.

### **BACKGROUND**

#### **A. The Parties**

Bicara is a public biopharmaceutical company pursuing clinical development of ficerafusp alfa (also known as BCA101), an antibody currently in clinical trials for the treatment of certain kinds of cancerous tumors. (*See* Compl. ¶¶ 52-53 (ECF No. 1).)

Biocon, an Indian pharmaceutical company, formed Bicara in 2018 as a wholly-owned subsidiary for the purpose of pursuing tumor-targeting antibodies like ficerafusp alfa. (Compl. ¶ 71-72.) In 2019, Biocon licensed its intellectual property relating to ficerafusp alfa and other fusion proteins (called “Copycat Biocon IP” in the Complaint, and here, the “Biocon IP”) to Bicara. (*Id.* ¶¶ 6 & n.2, 73.) As alleged in the Complaint, by at least 2023, Bicara brought in additional investors and eventually went public in 2024. (*Id.* ¶¶ 68, 74.)

Y-Trap claims to be a “start-up biotechnology” company pursuing the development of cancer-treating proteins. (*Id.* ¶ 1.) Y-Trap alleges that in 2010, prior to the creation of Y-Trap, its founders, Dr. Atul Bedi and Dr. Rajani Rani, invented certain technology relating to fusion proteins, including “a patent family represented by PCT/US2011/027317” (the “Bedi IP”). (Compl. ¶¶ 2 & n.1, 26.) The Complaint alleges that all of the Bedi IP was assigned to JHU<sup>2</sup> and

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<sup>2</sup> JHU is not a party to this action, and the Complaint provides no explanation for its absence.

that JHU subsequently licensed the Bedi IP to Y-Trap. (*Id.* ¶¶ 2, 85.)<sup>3</sup>

**B. Y-Trap’s Founders’ Alleged Invention of “Fusion Proteins” that Combine Disabling “TGF- $\beta$ ” with Targeting “EGFR.”**

According to the Complaint, Bedi and Ravi made discoveries in 2010 and 2011 relating to “fusion proteins” designed to target tumors and cancer cells by fusing a targeting antibody to an immunomodulatory (*i.e.*, immune system modifying) antibody. (Compl. ¶ 26.) The Complaint further alleges that the invention includes fusion proteins in which the targeting antibody “binds epidermal growth factor receptor (EGFR)” and the immunomodulatory antibody “is a specific ligand-binding sequence of the extracellular domain” of “transforming growth factor-beta receptor II (TGF $\beta$ RII).” (Compl. ¶¶ 4, 26, 29-34.) The Complaint further alleges that these alleged inventions are embodied in the Bedi IP, and thus, licensed to Y-Trap. (*Id.*)

The crux of Y-Trap’s complaint is an allegation that the Biocon IP describes “the same EGFR/TGF $\beta$ -binding fusion protein described in the first provisional [patent application] of the [] Bedi IP.” (*Id.* ¶ 41.) Despite acknowledging that Biocon first began making supposed “copycat” patent filings as early as 2012, (*id.* ¶ 40), the Complaint asserts that Y-Trap “reasonably believe[d]” by 2014 “that Biocon stopped its efforts to interfere with the [] Bedi IP and/or to compete with Y-Trap’s licensing and development efforts for its fusion proteins.” (*Id.* ¶ 50.) The remaining allegations of the Complaint, however, as well as documents judicially noticeable here, belie that assertion, and this bald assertion need not be credited, even on a motion to dismiss.

**C. Biocon’s Decade-Long Public Development of the Biocon IP Toward Fusion Proteins that Combine Disabling “TGF- $\beta$ ” with Targeting “EGFR.”**

Beginning in 2013 with the international patent application PCT/IB2013/001155, Biocon

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<sup>3</sup> While the Complaint alleges that Y-Trap’s founders had prior dealings with Biocon before Y-Trap’s formation, (*see, e.g., id.* ¶¶ 27-34), there are no allegations in the Complaint that Bicara was involved in those activities.

has been developing and prosecuting the Biocon IP for over ten years. The Complaint itself lists out the numerous U.S. patents that Biocon has obtained as part of the Biocon IP. (*See* Compl. ¶ 6 & n.2 (listing patent applications and patents); *see also* Report on Filing of Action Regarding Patent (ECF No. 3 (listing all patents and issuance dates).) The first Biocon patent, U.S. Patent No. 8,815,247 (the “Biocon ’247 patent”), issued on August 26, 2014. (Ex. 1.)<sup>4</sup> Since that time, eight additional patents issued out of the same family as the Biocon ’247 patent in the United States (collectively with the Biocon ’247 patent, the “Biocon Patents”). (Exs. 2-9.) Notably, six patents in this family *issued*, and nine patent applications in this family *published, more than four years* before the Complaint:

Patent Number	Publication Date	Issue Date	Holder of Patent
8,815,247	10/31/2013	8/26/2014	Biocon Ltd.
9,340,617	12/4/2014	5/17/2016	Biocon Ltd.
9,758,582	8/18/2016	9/12/2017	Biocon Ltd.
9,809,651	6/16/2016	11/7/2017	Biocon Ltd.
10,144,934	8/17/2017	12/4/2018	Biocon Ltd.
10,385,348	3/8/2018	8/20/2019	Biocon Ltd.
11,028,399	12/5/2019	6/8/2021	Biocon Ltd.
11,060,097	6/6/2019	7/13/2021	Biocon Ltd.
12,049,632	4/16/2020	7/30/2024	Biocon Ltd.

Moreover, these Biocon Patents are directed to “fusion proteins” in the same realm the Complaint alleges the Bedi IP is directed to, with the Complaint using language that appears drawn directly from the Biocon Patents’ claims (all emphasis added):

Ex. 6 (U.S. Patent No. 10,385,348) Claim 1 (issued Aug. 20, 2019)	Complaint ¶ 4 (filed Oct. 22, 2024)
claiming a “method of <b>reducing tumor</b> Transforming growth factor-beta (TGF-β) levels ... with a therapeutic amount of a	alleging Bedi IP describes “ <b>promot[ing] antitumor immunity</b> ” with “ <b>fusion proteins</b> comprising ... an <b>immunomodulatory</b>

<sup>4</sup> All numbered exhibits are exhibits to the Declaration of Daryl Wiesen. The Court may consider the content of “documents incorporated by reference in the complaint,” such as patents, as well as “matters of public record, and other matters susceptible to judicial notice.” *See, e.g., Squeri v. Mount Ida Coll.*, 954 F.3d 56, 61 (1st Cir. 2020); *Ocean Semiconductor LLC v. Analog Devices, Inc.*, 664 F. Supp. 3d 195, 201 (D. Mass. 2023) (considering patents referenced in complaint).

chimeric fusion protein ... wherein the immunomodulating moiety is TGFβRII ... and wherein the targeting moiety is an Anti-EGFR1 antibody”	moiety that binds and disables ... TGF-β” and “targeting antibody that binds ... EGFR.”
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According to the Complaint itself, and therefore to be accepted for purposes of this Motion, all of the Biocon Patents, issued years ago, contain claims touching on these or related subjects.<sup>5</sup> Indeed, every U.S. Bedi IP-related patent identified in the Complaint, including U.S. Patent No. 8,993,524 (the “Bedi ’524 patent”), the first U.S. patent issued out of the Bedi IP, lists the Biocon ’247 patent on its face as a cited reference. Indeed, in the Notice of Allowance for the Bedi ’524 patent, dated November 24, 2014, the Examiner noted the relevance of the Biocon ’247 patent, listing it as prior art of record. (*See* Ex. 12 (Notice of Allowability) at 4.) And then, during prosecution of each subsequent Bedi patent in the family, the applicant (*i.e.*, Bedi) listed the Biocon ’247 patent as relevant subject matter on an Information Disclosure Statement. (*See* Exs. 13-17.)

**D. Bicara’s Longstanding and Public Development of Ficerafusp Alfa, a “Bifunctional EGFR/TGFβ Fusion Protein.”**

As noted above, as alleged in the Complaint, in 2018, Biocon formed Bicara as a wholly-owned subsidiary to develop ficerafusp alfa and other fusion proteins connected to the Biocon IP, and, in 2019, Biocon licensed the Biocon IP to Bicara. (Compl. ¶¶ 72-73.)

On June 6, 2020, Bicara posted information concerning its Phase 1/1b trial of ficerafusp

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<sup>5</sup> *See, e.g.*, Ex. 1 (U.S. Patent No. 8,815,247) (claiming a “fusion protein comprising at least one targeting moiety to target a cancer cell and at least one immunomodulating moiety that counteracts immune tolerance”); Ex. 2 (U.S. Patent No. 9,340,617) (claiming a “fusion protein ... wherein the immunomodulating moiety is TGF-βRII”); Ex. 3 (U.S. Patent No. 9,758,582) (claiming a “fusion protein ... wherein the immunomodulating moiety is TGF-βRII”); Ex. 4 (U.S. Patent No. 9,809,651) (claiming a “method of treating cancer ... with a therapeutic amount of chimeric fusion protein ... wherein the immunomodulating moiety is TGF-βRII ... and wherein the targeting moiety consists of a light chain of an Anti-EGFR1 antibody”); Ex. 5 (U.S. Patent No. 10,144,934) (claiming a “method of preparing a therapeutically active antibody-peptide fusion protein ... wherein the immunomodulating moiety is TGF-βRII ...; wherein the targeting moiety is selected from the group consisting of an Anti-EGFR1 antibody”).

alfa on ClinicalTrials.gov. (Ex. 11 <https://clinicaltrials.gov/study/NCT04429542>.)<sup>6</sup> The trial's title states it was the "First-in-Human" study of "Bifunctional EGFR/TGFβ Fusion Protein BCA101" and focused on "Patients With EGFR-Driven Advanced Solid Tumors." (*Id.*) The filing further identified "Bicara Therapeutics" as the study sponsor. (*Id.*)

On March 15, 2021, Bicara issued a press release announcing it was being spun out of Biocon to develop ficerafusp alfa. (Compl. ¶¶ 52, 65; *id.* Ex. B.) Bicara proceeded to raise money with additional investors through private Series B and Series C offerings through 2023 and an initial public offering in September 2024. (*Id.* ¶¶ 12, 68, 74-75.)

That is all the Complaint alleges Bicara has done: (1) license the Biocon IP while (in 2019) a wholly-owned subsidiary of Biocon; (2) investigate a drug candidate out of the Biocon IP; and (3) raise funds to support those efforts. Y-Trap does not plead that Y-Trap (or its founders) have ever had any interaction with Bicara, directly or indirectly. The Complaint also lacks any allegation that Bicara (or anyone on its behalf) has ever interacted with any potential investor, customer, or supplier of Y-Trap, made any negative statement concerning Y-Trap, the Bedi IP, Dr. Bedi, or Dr. Rani, or sought to affect Y-Trap's position in the marketplace.

**E. Years Later (and Within Weeks of Bicara's IPO), Y-Trap Files This Action, Alleging It Was Wrongful to Patent and Develop EGFR/TGFβ Fusion Proteins.**

Nevertheless, on October 22, 2024, Y-Trap filed the Complaint. Y-Trap brings three claims against Bicara: (1) unfair competition pursuant to M.G.L. ch. 93A (Count III), (2) unjust enrichment (Count IV), and (3) civil conspiracy with Biocon (Count VI). The lynchpin of Y-

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<sup>6</sup> As public records subject to judicial notice, the Court may consider documents filed on ClinicalTrials.gov on a motion to dismiss. *See, e.g., Squeri*, 954 F.3d at 61; *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at \*22 (S.D.N.Y. May 29, 2013) ("[I]t is appropriate to review the versions of the studies' designs as published and available online through the National Institutes for Health at ClinicalTrials.gov" at the motion to dismiss stage).

Trap’s claims is its theory underlying the inventorship claim brought against Biocon (Count I).

As Y-Trap tells it, because of the alleged overlap in subject matter between the Bedi IP and the Biocon IP, Y-Trap claims that Bedi and Rani are the proper inventors of the Biocon IP. (*Id.* ¶¶ 25-26, 29-34, 39-44.) From that initial premise, Y-Trap alleges the Biocon IP is a **subset** of the Bedi IP, and so, through an unexplained daisy-chain of assignment and license that Y-Trap uses to claim rights to the Bedi IP, Y-Trap argues that it has rights to the Biocon IP as well, including the Biocon Patents. The Complaint does not allege that Y-Trap has any other legal rights to the Bedi IP or the Biocon IP—it has no interest in trade secrets (the Bedi IP has long-since published its patent applications)—nor does Y-Trap allege rights to any confidentiality agreements involving JHU or any other person or entity. Y-Trap’s alleged license to the Biocon IP is the sole basis of Y-Trap’s assertion that any action by Bicara was wrongful.

### **LEGAL STANDARD**

Under Federal Rule of Civil Procedure 8, “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Sceviour v. McKeon*, 2018 WL 3352964, at \*1 (D. Mass. July 9, 2018) (O’Toole, J.) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). “Legal conclusions and bare recitals of the elements of a cause of action are disregarded.” *Id.* (citing *Mead v. Indep. Ass’n*, 684 F.3d 226, 231 (1st Cir. 2012)). “The remaining factual statements[,] taken as true,” must give rise to “a reasonable inference of liability for the misconduct alleged.” *Id.* (citing same). To survive dismissal, a complaint must allege more than “just a ‘formulaic recitation of the elements of a cause of action.’” *Rosa v. PNC Mortg.*, 2017 WL 4176971, at \*1 (D. Mass. Sept. 21, 2017) (O’Toole, J.) (quoting *Iqbal*, 556 U.S. at 678).

The court may grant a motion to dismiss based on the statute of limitations where “it is plain on the face of [plaintiff]’s complaint that [the] claims are time-barred,” *Awadh v. Tourneau, Inc.*, 2018 WL 1318921, at \*3 (D. Mass. Mar. 14, 2018); *see also Martin v. Somerset Cnty.*, 86



F.4th 938, 942 (1st Cir. 2023) (“Entering a judgment on a motion to dismiss . . . based on a limitations defense is entirely appropriate when the pleader’s allegations leave no doubt that an asserted claim is time-barred.”). Similarly, issues of preemption are also appropriate to consider at the motion to dismiss stage. *See Lyons v. Gillette*, 882 F. Supp. 2d 217, 233 (D. Mass. 2012) (granting motion to dismiss in part because claims were preempted).

### **ARGUMENT**

Even taking the allegations of the complaint as true for purposes of this motion, Y-Trap’s claims against Bicara fail for at least three independent reasons. First, each of the claims is time barred. Second, Y-Trap fails to plead one or more of the required elements of each of its claims against Bicara. Third, all of the claims are preempted by federal patent law.<sup>7</sup>

#### **I. Y-Trap’s Claims Against Bicara Are Barred by the Statutes of Limitations.**

All three of Y-Trap’s claims against Bicara fall outside of the relevant statutes of limitations. For Y-Trap’s unjust enrichment (Count IV) and civil conspiracy (Count VI) claims, the Complaint directly pleads that those causes of action accrued more than three years ago—the relevant statutory period. The Complaint itself *attaches* a press release from more than three years ago that would have put Y-Trap on notice of its claims. For Y-Trap’s Chapter 93A claim, the statutory period is four years. But there again, the Complaint contains ample allegations putting Y-Trap on notice of this purported claim years earlier. The Biocon Patents have been continuously, and publicly, prosecuted for *years* before Y-Trap finally chose to file its Complaint. There is no excuse for Y-Trap waiting over a decade to finally bring its claims.

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<sup>7</sup> Bicara does not appear to be a defendant under Y-Trap’s claim for correction of inventorship (Count I). However, Bicara understands that Biocon intends to move to dismiss that count for failure to state a claim, and Bicara joins in those arguments. Because the only basis for this Court’s jurisdiction is the federal question raised by the inventorship claim, Compl. ¶¶ 18-19, if that claim is dismissed, the claims against Bicara should be dismissed for lack of subject matter jurisdiction.

**A. Each of Y-Trap’s Alleged Claims Against Bicara Are Subject to a Three- or Four-Year Statute of Limitations.**

In Massachusetts,<sup>8</sup> civil conspiracy based on a tort is subject to a three-year statute of limitations. M.G.L. ch. 260, § 2A; *Kaiser v. Kirchick*, 662 F. Supp. 3d 76, 94 (D. Mass. 2023). Similarly, because Y-Trap pleads no contract claims against Bicara, its unjust enrichment claim is also subject to a three year statute of limitations. M.G.L. ch. 260, § 2A; *Epstein v. C.R. Bard, Inc.*, 2004 WL 1598912, at \*3 (D. Mass. July 19, 2004). Thus, the critical date for limitations purposes for these claims is October 22, 2021, three years before the filing of Y-Trap’s Complaint.

Y-Trap’s final claim against Bicara comes under M.G.L. ch. 93A, which is subject to a four year statute of limitations. M.G.L. ch. 260, § 5A; *Latson v. Plaza Home Mortg., Inc.*, 708 F.3d 324, 326 (1st Cir. 2013). Thus, for limitations purposes, the earliest critical date relevant to all of Y-Trap’s claims is October 22, 2020, four years before its Complaint.

**B. All of Y-Trap’s Alleged Claims Against Bicara Arose More than Four Years Prior to Filing the Complaint.**

The source of Y-Trap’s three state law claims against Bicara is a theory that the existence and development of the so-called “copycat” Biocon Patents harmed Y-Trap, either because (1) Y-Trap alleges it should have rights to the Biocon Patents themselves as part of the Bedi IP or (2) because the existence of the Biocon Patents somehow harms the Bedi IP patents. (*See, e.g.*, Compl.

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<sup>8</sup> The Complaint alleges (in a conclusory fashion) that Bicara’s supposedly wrongful actions have occurred “substantially in Massachusetts,” and that Y-Trap has been harmed “in Massachusetts.” (Compl. ¶¶ 117, 126.) Y-Trap also expressly seeks the protection of Massachusetts law with its Chapter 93A claim. For purposes of this Motion, Bicara assumes Massachusetts law applies. *See Levin v. Dalva Bros., Inc.*, 459 F.3d 68, 74 (1st Cir. 2006) (Massachusetts takes a “functional approach to choice of law” grounded in “the Restatement (Second) of Conflict of Laws (1971)”). Choosing Delaware law (Y-Trap’s state of incorporation) or California law (Y-Trap’s principal place of business) would not change this analysis. *See Streetwater Point, LLC v. Kee*, 2020 WL 6561567, \*7-\*8 (Super. Del. 2020) (unjust enrichment; 3 years); *Tusha v. Pediatric Associates, P.A.*, 2022 WL 823583, \*4 (D. Del. 2022) (civil conspiracy; 3 years); *Federal Deposit Ins. Corp. v. Dintino*, 167 Cal. App. 4th 333, 347 (Cal. App. 2008) (unjust enrichment; 3 years); *Suber v. VVP Services, LLC*, 2023 WL 8143876, \*4 (C.D. Cal. 2023) (civil conspiracy; 3 years).

¶ 122 (“repeated and baseless claims of inventorship and ownership of the [ ] Bedi IP”); *id.* ¶ 131 (“Bicara [is] unjustly enriched by licensing the [Biocon Patents], by receiving the benefit of the false statements made by Biocon related to inventorship and ownership of the [ ] Bedi IP....”).) Similarly, Y-Trap alleges its Chapter 93A claim arises because Bicara is pursuing “bifunctional EGFR/TGF- $\beta$ RII-binding fusion proteins ... through Biocon” and the Biocon IP. (Compl. ¶¶ 121-22.)

But Biocon’s prosecution of the Biocon Patents and Bicara’s development of ficerafusp alfa long predate October 2020. *Nine* of the applications for the Biocon Patents published prior to October 2020, and the USPTO *issued six Biocon Patents* prior to October 2020. *Supra* at 5-6. Biocon’s prosecution of those patents started the clock on the limitations period upwards of a decade ago. (*See, e.g.*, Ex. 4 (U.S. Patent No. 9,809,651) (issued Nov. 7, 2017) (claiming “treating cancer” with “fusion protein” comprising “TGF- $\beta$ RII” and “Anti-EGFR1 antibody”).)

Even on a motion to dismiss, Y-Trap is charged with knowing these facts. *See Gattineri v. Williams-Sonoma Stores, Inc.*, 223 N.E.3d 1237, 2023 WL 8888648, at \*2 (Mass. App. Ct. 2023) (affirming dismissal of claim, including under M.G.L. ch. 93A; “[t]he issuance of a patent on a pan matching her invention in 2010 triggered the statutes of limitations on her claims.”). But more than that, because Biocon’s ’247 patent is a cited reference *on the face* of Y-Trap’s allegedly licensed Bedi IP patents, Y-Trap was not just hypothetically aware of Biocon’s continual patent prosecution, it was *specifically on notice* that this patent family was being developed at least as early as November 2014, well outside of the statute of limitations for these claims. *See Stark v. Advanced Magnetics, Inc.*, 736 N.E.2d 434, 442 (Mass. App. Ct. 2000) (finding that issuance of patent and annual report “were sufficient to alert the plaintiff that AMI was in breach of its alleged agreement with him and that he had been harmed” and that his claims under M.G.L. ch. 93A were

brought outside of the statute of limitations).<sup>9</sup> Y-Trap’s gambit to play possum for years, only to spring a lawsuit the moment Bicara went public fails. These claims are years too old.<sup>10</sup>

Beyond the patent record, Bicara’s *clinical* development of ficerafusp alfa predates October 2020 as well. On June 6, 2020, Bicara publicly posted information concerning its Phase 1/1b trial of ficerafusp alfa on ClinicalTrials.gov, describing the study as an investigation of a “Bifunctional EGFR/TGFβ Fusion Protein.” (Ex. 10.) Thus, Y-Trap’s now-claim that it is somehow wrongful for Bicara to pursue the development of an “EGFR/TGFβ-binding fusion protein,” (Compl. ¶ 4), arose outside the limitations period.

Further, the Complaint *attaches* a press release dated March 15, 2021 that described Bicara’s development of ficerafusp alfa, included Bicara’s statement that it has “all rights and licenses” to the relevant intellectual property, and noted Bicara’s partnership with Biocon. (Compl. ¶ 65, Ex. B.) These facts are all central to Y-Trap’s claims, and, in addition to the above facts, independently render the unjust enrichment and civil conspiracy claims time barred. (See Compl. ¶¶ 9, 11 (alleging Y-Trap’s claims against Bicara stem from (1) “Biocon licensed to Bicara

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<sup>9</sup> See also *Wise v. Hubbard*, 769 F.2d 1, 2 (1st Cir. 1985) (“[The district court] ruled that the issuance of a patent and its recordation in the Patent Office was notice to the world of its existence and held that the three-year Massachusetts statute of limitations, M.G.L.A. ch. 260, § 2A (1985), which the parties agreed was controlling, started to run on July 23, 1974, when the patent was issued and recorded.”); *Beta Pharma, Inc. v. Inventis Biotechnology (Shanghai) Co.*, 2024 WL 5286240, \*4 (D.N.J. Dec. 31, 2024) (dismissing trade secret claim because “statute of limitations began to run” with publication of patent applications).

<sup>10</sup> Indeed, nothing stood in the way of contesting the Biocon Patents all those years ago. Likely not coincidentally, *in November 2015*, JHU petitioned for *inter partes* review of claim 1 of U.S. Patent No. 8,815,247, the first Biocon patent, arguing that claim was anticipated or rendered obvious by one of the Bedi patents, U.S. Patent No. 8,993,524. *The John Hopkins Univ. v. Biocon Ltd.*, IPR2016-00175, Paper No. 1 (P.T.A.B. Nov. 10, 2015). The PTAB denied institution, finding that JHU “fail[ed] to show that there is a reasonable likelihood that Petitioner would prevail” in establishing invalidity of claim 1. *Id.*, Paper No. 9 at 10. Particularly relevant here, the PTAB found that there are differences between the fusion protein disclosed in Bedi’s ’524 patent and the fusion protein disclosed in the Biocon ’247 patent, determining not to institute on the basis of anticipation. *Id.* at 7.

the [] Biocon IP” and (2) “Bicara promoted BCA101 ... and falsely presented [BCA101] as [Bicara’s] own to investors, partners, the oncology community, and the public”).) *See also Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1553 (Fed. Cir. 1996) (finding plaintiff had notice of infringement when defendant advertised in trade magazines and attended trade shows).

Y-Trap cannot point to some later-in-time event (*e.g.*, Bicara’s 2024 initial public offering) to avoid the limitations period either. “The plaintiff need not know the full extent of its injury for a cause of action to accrue and for the statute of limitations to begin running.” *Taygeta Corp. v. Varian Assocs., Inc.*, 763 N.E.2d 1053, 1063 (Mass. 2002). The key is that the plaintiff “knows, or reasonably should have known, that it has been harmed or may have been harmed.” *Id.* Here, that “reasonable” knowledge occurred, at the very least, with each issuance of a Biocon Patent in 2014, 2016, 2017, 2018, and 2019, as well as with the public notification by Bicara of its clinical trial concerning ficerafusp alfa in June 2020. With those events, Y-Trap knew or should have known of the continued prosecution of the Biocon Patents, the ongoing development of ficerafusp alfa, and the representations that Y-Trap had no rights to those patents and products well outside the statutory period. Each of Y-Trap’s supposed claims were triggered by these pre-critical-date events.<sup>11</sup> Y-Trap cannot avoid dismissal on this ground.

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<sup>11</sup> For instance, the only aspect of Bicara’s IPO documents that Y-Trap takes issue with is that those documents imply that the Bedi IP does not encompass ficerafusp alfa. (Compl. ¶ 66.) Y-Trap’s claim that Bicara’s IPO documents are “false and misleading” is completely inaccurate—indeed, the prospectus **discloses** that “in August 2024, we received a letter alleging ficerafusp alfa infringes certain third party patents.” (Ex. 11, <https://www.sec.gov/Archives/edgar/data/2023658/000119312524217265/d821336ds1a.htm>, cited in ¶ 66). But for limitations purposes, the Biocon Patent filings contain the **same** assertion Y-Trap takes issue with—that Bedi did not invent the IP claimed in those patents. No “new” harm could be created by repeating what has been disclosed on the face of the Biocon Patents for over a decade.

## **II. All Counts Against Bicara Should Be Dismissed Because the Complaint Fails to Plead the Elements of Its Claims.**

A second, independent ground for dismissal is that the Complaint does not sufficiently plead all of the elements of any of the three state law claims that Y-Trap brings against Bicara.

### **A. Y-Trap Fails to Plead the Elements of a Violation of Chapter 93A (Count III).**

Y-Trap’s claim that Bicara violated Chapter 93A (Count III) fails. As an initial matter, a claim under Section 11 of Chapter 93A “requires that there be a commercial transaction between a person engaged in trade or commerce with another person engaged in trade or commerce.” *Farsheed v. Syed*, 2014 WL 2861801, at \*6 (Mass. App. Ct. June 25, 2014).<sup>12</sup> In addition, a plaintiff must allege (1) “the defendant engaged in an unfair method of competition or committed an unfair deceptive act or practice”; (2) “a loss of money or property was suffered”; and (3) causation of that loss. *Anoush Cab, Inc. v. Uber Techs., Inc.*, 8 F.4th 1, 16 (1st Cir. 2021) (citing M.G.L. ch. 93A §§ 2, 11). Here, Y-Trap fails to allege any of these requirements.<sup>13</sup>

#### **1. Y-Trap Does Not Allege the Required Commercial Transaction with Bicara.**

Even taking the Complaint as true, Y-Trap does not allege that Bicara engaged in the required commercial transaction with Y-Trap. *See Farsheed*, 2014 WL 2861801, at \*6. In attempting to make out its claims, Y-Trap points to only the following actions: (1) Bicara entered

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<sup>12</sup> Section 11 of Chapter 93A (rather than the consumer statute, Section 9) applies here because Y-Trap is a “person who engages in the conduct of any trade or commerce.” (*See, e.g.*, Compl ¶ 110 (“Y-Trap ... participate[s] in the pharmaceutical product industry, and in particular, in the business of developing novel therapeutics for cancer therapy.”).)

<sup>13</sup> To maintain a claim under Section 11, a plaintiff must also prove that the unfair or deceptive trade practice took place “primarily and substantially” within Massachusetts. M.G.L. ch. 93A, § 11. While Bicara is not moving to dismiss on that ground through this Motion, Y-Trap will ultimately not be able to prove that the conduct at issue in the Complaint occurred primarily and substantially in Massachusetts. *See Bushkin Assocs., Inc. v. Raytheon Co.*, 473 N.E.2d 662, 672 (Mass. 1985) (affirming summary judgment for defendants because plaintiff did not show “primary involvement with Massachusetts”).

into the Contract Transfer and License Agreement and other agreements with Biocon (Compl. ¶¶ 73-83), (2) Bicara is developing ficerafusp alfa (*id.* ¶ 68), and (3) Bicara raised money in series B and C fundraisers and an initial public offering (*id.* ¶ 12). None of these alleged actions qualify as a commercial transaction between persons engaged in trade or commerce, namely, with Y-Trap, as required to bring a claim under Chapter 93A, § 11.

Fatal to Y-Trap’s Chapter 93A claim is that Y-Trap and Bicara never engaged in a commercial transaction together. “In order for a violation under §§ 2 and 11 to hold water, a commercial interaction must have taken place *between* the parties and they must have been acting within a business context.” *JT IP Holding, LLC v. Florence*, 2024 WL 4190044, at \*11 (D. Mass. Sept. 12, 2024) (emphasis added); *see also Szalla v. Locke*, 657 N.E.2d 1267, 1269 (Mass. 1995) (“we conclude that ch. 93A requires that there be a commercial transaction *between* a person engaged in trade or commerce with another person engaged in trade or commerce”) (emphasis added); *L.B. Corp. v. Schweitzer-Mauduit Int’l, Inc.*, 121 F. Supp. 2d 147, 151-52 (D. Mass. 2000) (granting summary judgment where there was no “transaction between the parties”) (citing cases). Those allegations are absent here. Y-Trap (1) is not a party to the license agreement or other agreements with Biocon;<sup>14</sup> (2) is not involved in the development of ficerafusp alfa; and (3) did not invest money in Bicara as part of Bicara’s series B and C financings or IPO. Y-Trap does not allege it has ever interacted with Bicara in *any* capacity. *John Beaudette, Inc. v. Sentry Ins. A Mut. Co.*, 94 F. Supp. 2d 77, 121 (D. Mass. 1999) (“In general, no commercial relationship exists where

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<sup>14</sup> Bicara’s agreements with Biocon, entered into while Bicara was alleged to be a wholly-owned subsidiary of Biocon, are separately not subject to challenge under Chapter 93A because they were entirely internal affairs. *Fossa, Ltd. v. I Jian Lin*, 2017 WL 4374483, at \*5 (D. Mass. Sept. 29, 2017) (citing *Milliken & Co. v. Duro Textiles, LLC*, 887 N.E.2d 244, 259 (Mass. 2008)) (“Section 11 of 93A is intended to apply to dealings between legally separate persons engaged in arm’s-length transactions.”).



the parties only contact occurs in the context of litigation.”). Thus, in the absence of any “commercial transaction” *between* Y-Trap and Bicara, Y-Trap’s claim under Chapter 93A must be dismissed. *JT IP Holding*, 2024 WL 4190044, at \*11.

## 2. The Complaint Does Not Allege that Bicara Committed an Unfair or Deceptive Trade Practice.

In order to bring a claim for unfair or deceptive trade practices under Section 11 of Chapter 93A, “the challenged misconduct must rise to the level of an ‘extreme or egregious’ business wrong, ‘commercial extortion,’ or similar level of ‘rascality’ that raises ‘an eyebrow of someone inured to the rough and tumble of the world of commerce.’” *Peabody Essex Museum, Inc. v. U.S. Fire Ins. Co.*, 802 F.3d 39, 54 (1st Cir. 2015). Y-Trap has not, nor could it, allege that Bicara’s actions rise to the necessary level of “extreme or egregious” behavior.

Y-Trap’s allegations against Bicara are limited to routine business practices. In contrast, the paradigmatic 93A case has some measure of malicious practice, like disregarding known contractual arrangements to extort, *Anthony’s Pier Four, Inc. v. HBC Assocs.*, 583 N.E.2d 806, 821-22 (Mass. 1991), causing retribution on a party by exercising contractual rights in bad faith, *Kattar v. Demoulas*, 739 N.E.2d 246, 257 (Mass. 2000), or misappropriation of known trade secrets, *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215, 243 (1st Cir. 2005). *See also Framingham Auto Sales, Inc. v. Workers’ Credit Union*, 671 N.E.2d 963, 965 (Mass. App. Ct. 1996) (collecting cases) (affirming rejection of Chapter 93A claim with “no ulterior motive, no coercive or extortionate objective”).<sup>15</sup> Against that backdrop, Y-Trap has only

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<sup>15</sup> While the Complaint alleges certain confidential communications between Y-Trap’s non-party founders and Biocon before Y-Trap’s formation (*see* Compl. ¶¶ 29-34), none of those allegations connect to *Bicara’s* actions, much less to any action cognizable under Chapter 93A. Moreover, Y-Trap asserts no rights in trade secrets or other confidential information—it expressly limits its rights in this case to the *patent* filings of Biocon (*id.* ¶ 86), and every aspect of the Bedi IP defined in the Complaint is no longer confidential; it all published long ago. (*Id.* ¶ 26.)



alleged Bicara has licensed certain patent rights with a third party (Biocon), developed ficerafusp alfa, a drug candidate related to that intellectual property, and raised money to support those efforts, at times stating (accurately) that it has a license to the Biocon Patents from the assignee to those patents (Biocon). There is no basis to suggest, for example, that Bicara's use of the Biocon Patents is "extreme or egregious" or exhibits "rascality." Biocon is the named assignee of every one of those patents as registered with the USPTO and has been for years. (Compl. ¶¶ 6 & n.2, 73.) These routine business practices, none of it targeted to Y-Trap, do not meet that statutory standard.

Courts have dismissed Chapter 93A claims for failure to plead an unfair or deceptive trade practice even where there is some sharp practice, itself lightyears apart from what Y-Trap alleges concerning Bicara here. *See, e.g., Whitehall Co. v. Merrimack Valley Distrib. Co.*, 780 N.E.2d 479, 483-87 (Mass. App. Ct. 2002) (no unfair or deceptive act or practice where defendant allegedly engaged in "price discrimination . . . forbidden by G.L. c. 138, § 25A" because "price discrimination without an adverse impact on competition, and not simply on competitors, is not an unfair method of competition or an unfair trade practice within the meaning of G.L. ch. 93A, § 2").<sup>16</sup> The Complaint simply contains nothing to support a Chapter 93A claim.

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<sup>16</sup> *See also Mass. Sch. of L. at Andover, Inc. v. Am. Bar Ass'n*, 952 F. Supp. 884, 891 (D. Mass. 1997) (no unfair or deceptive practice where plaintiff alleged defendant's inaccurate statements "caused confusion and understanding" but "ple[d] no facts to support a finding that such misstatement had any anticompetitive effect" because "unfair competition within the meaning of ch. 93A requires a showing of more than injury to a single customer or other business caused by isolated conduct"), *aff'd*, 142 F.3d 26 (1st Cir. 1998); *Citibank, N.A. v. Najda*, 2016 WL 158502, at \*3-4 (D. Mass. Jan. 13, 2016) (no unfair or deceptive act where plaintiff did "not ple[ad] facts that show [defendant's] . . . notices were false or deceptive" because the communication was not "inaccurate . . . , let alone . . . unethical or oppressive"), *aff'd*, 2024 WL 4257837 (1st Cir. July 12, 2024).

### 3. The Complaint Does Not Allege that Y-Trap Suffered a Loss of Money or Property.

Chapter 93A requires that the Complaint allege that “a loss of money or property was suffered.” *See Anoush Cab*, 8 F.4th at 16 (citing M.G.L. ch. 93A §§ 2, 11). “‘Money’ means money, not time, and . . . ‘property’ means the kind of property that is purchased or leased, not such intangibles as a right to a sense of security, to peace of mind, or to personal liability.” *Arthur D. Little, Inc. v. Dooyang Corp.*, 147 F.3d 47, 56 (1st Cir. 1998) (citing *Baldassari v. Public Fin. Trust*, 337 N.E.2d 701, 709 (Mass. 1975)). Here, Y-Trap’s Complaint does not include a single allegation that it lost any tangible money or property as a direct result of Bicara’s actions.

The only injury the Complaint attributes to its Chapter 93A claim against Bicara is an alleged intangible “loss and diminution of [Y-Trap’s] competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace.” (Compl. ¶ 127.)<sup>17</sup> That is plainly insufficient; intangible loss of market share or market opportunity are not compensable under Section 11 of Chapter 93A. *IDT Telecom, Inc. v. Voice Dists., Inc.*, 2008 WL 1800102, at \*1 (Mass. Super. Ct. Apr. 11, 2008) (“It is clear that a purported loss of ‘market share’ in and of itself is an intangible not compensable under [M.G.L. ch. ] 93A, § 11....”); *Ratchford v. Orange Lantern, Inc.*, 720 F. Supp. 3d 64, 78 (D. Mass. 2024) (finding no “loss of money or property” in unauthorized use of images where purported loss included lost opportunity to be paid for images’ use and purported misimpression of affiliation

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<sup>17</sup> In the Chapter 93A count directed to Biocon, Y-Trap alleges that “Y-Trap’s Massachusetts-based partner pulled out of the agreement due to the uncertainty manufactured by Bicara regarding the Bedi IP.” (Compl. ¶ 117.) It is unclear whether this allegation is intended to support Y-Trap’s Chapter 93A claim against Bicara. In any event, the allegation fails to identify whether Y-Trap suffered any “loss of money or property” (did Y-Trap find a non-Massachusetts-based partner?) or what actual act of Bicara supposedly generated this harm. For instance, the Complaint does not allege Bicara has commented on the Bedi IP.

between plaintiffs and defendant). Even if an undifferentiated loss of competitive position could be addressable through Chapter 93A, Y-Trap does not even plead it *sells* a product in the marketplace, let alone plead facts that it in actuality possesses a “competitive position” that *could* be harmed. (And Bicara, for its part, as a clinical-stage pharmaceutical company, has no product at this time either.)

**4. The Complaint Does Not Allege that Any Action by Bicara Caused Any Effect Felt by Y-Trap.**

Finally, to the extent Y-Trap has alleged that Bicara’s use of and license to the Biocon IP forms a basis for its Chapter 93A claim, these allegations are also insufficient because there are no allegations in the Complaint explaining how Bicara’s legally obtained license and legal use of the Biocon IP have caused any loss at all to Y-Trap. *Gorbey ex rel. Maddox v. Am. J. of Obstetrics & Gynecology*, 849 F. Supp. 2d 162, 165 (D. Mass. 2012) (“[C]ausation is a required element of a successful Chapter 93A claim.” (quoting *Aspinall v. Philip Morris Co., Inc.*, 813 N.E.2d 476 (Mass. 2004))), *aff’d sub nom. A.G. ex rel. Maddox v. Elsevier, Inc.*, 732 F.3d 77 (1st Cir. 2013)). “To prevail on a Chapter 93A claim of this sort, the ‘plaintiff *must prove causation*—that is, the plaintiff is required to prove that the defendant’s unfair or deceptive act caused an adverse consequence or loss.’” *Jane Doe No. 1 v. Backpage.com, LLC*, 817 F.3d 12, 24 (1st Cir. 2016) (emphasis added) (affirming dismissal of Chapter 93A claim) (quoting *Rhodes v. AIG Domestic Claims, Inc.*, 461 Mass. 486, 961 N.E.2d 1067, 1076 (2012)); *see also id.* (“This requirement entails showing both ‘a causal connection between the deception and the loss and that the loss was foreseeable as a result of the deception.’” (quoting *Smith v. Jenkins*, 732 F.3d 51, 71 (1st Cir. 2013))). “In other words, the plaintiff must lay the groundwork for findings of both actual and proximate causation.” *Id.* “If an examination of the claim leads to the conclusion that it fails plausibly to allege a causal chain sufficient to ground an entitlement to relief, that claim is

susceptible to dismissal under Rule 12(b)(6).” *Id.*

Here, the Complaint includes only conclusory allegations about harm to Y-Trap. (*See* Compl. ¶ 127 (alleging that “Bicara’s activities are causing and will continue to cause severe and irreparable injury to Y-Trap”); *id.* ¶ 128 (alleging that “Bicara’s activities have directly and proximately caused significant damage to Y-Trap”); *id.* ¶ 117 (alleging “Massachusetts-based partner pulled out of” agreement “due to the uncertainty manufactured by Bicara regarding the Bedi IP”).) At most, these allegations amount to conclusory assertions that Bicara’s actions must have, somehow, without any explanatory mechanism, caused harm to Y-Trap. But the Complaint does not show how Y-Trap’s “loss was foreseeable” or “lay the groundwork” to show *how* Bicara caused Y-Trap’s harm. *See Backpage.com*, 817 F.3d at 24. Nor does the Complaint provide any specificity about what alleged actions Bicara engaged in that resulted in damage to Y-Trap. Thus, the allegations in the Complaint do not “provide, at the very least, some facts from which the Court could reasonably infer that Bicara’s action caused Y-Trap’s alleged harm and, therefore, Y-Trap’s 93A claim should be dismissed. *Gorbey*, 849 F. Supp. 2d at 166 (“plaintiffs’ complaint fails to state a cause of action under Chapter 93A with respect to any of the defendants because it does not connect the claimed injury to an alleged deceptive or unfair act”).

#### **B. Y-Trap Fails to Plead the Elements of Unjust Enrichment (Count IV).**

Y-Trap’s claim against Bicara for unjust enrichment (Count IV) also fails. “Unjust enrichment is the retention of money or property of another against the fundamental principles of justice or equity and good conscience.” *Columbia Plaza Assocs. v. Ne. Univ.*, 227 N.E.3d 999, 1018 (Mass. 2024) (citing *Sacks v. Dissinger*, 178 N.E.3d 388 (Mass. 2021)). To plead a claim for unjust enrichment in Massachusetts, “a plaintiff must show (1) a benefit conferred upon defendant by plaintiff, (2) appreciation or knowledge by defendant of the benefit, and (3) the acceptance of the benefit under the circumstances would be inequitable without payment for its

value.” *In re Shields Health Care Grp., Inc. Data Breach Litig.*, 721 F. Supp. 3d 152, 165 (D. Mass. 2024). Furthermore, the benefit itself must be unjust. *Metro. Life Ins. Co. v. Cotter*, 984 N.E.2d 835, 851 (Mass. 2013). Whether a benefit was unjust “turns on the reasonable expectations of the parties.” *Id.* at 850. Unjust benefits include those “involving fraud, bad faith, violation of a trust, or breach of a duty; ... business torts such as unfair competition and claims for infringement of trademark or copyright; and in some circumstances, ... disputes arising from quasicontractual relations.” *Id.* at 851. Here, the Complaint does not allege Y-Trap conferred any benefit on Bicara or that, even if there was some alleged benefit, that benefit was unjust.

The Complaint alleges only (and in conclusory fashion) that **Biocon** (not Y-Trap) conferred a benefit on Bicara. (Compl. ¶ 132.) The Complaint does not include any allegations at all that Y-Trap conferred a benefit to Bicara.<sup>18</sup> Accordingly, Y-Trap’s “claim for unjust enrichment [] fails as a matter of law” because it “does not establish a monetary or property benefit that [Y-Trap] conferred on [Bicara].” *Columbia Plaza Assocs.*, 227 N.E.3d at 1018.

Furthermore, the Complaint does not include any allegations that the alleged benefit to Bicara (the license to the Biocon patents, Complaint ¶ 131) was unjust. Indeed, there is nothing unjust about Bicara entering into a license agreement with Biocon, the assignee of the Biocon IP. The Complaint does not allege any fraud, bad faith, violation of trust, or breach of a duty by Bicara. *See Metro. Life Ins.*, 984 N.E.2d at 851. Y-Trap attempts to plead unfair competition but, as explained above, that claim fails. *Supra* at § II(A)(2); *see Vieira v. First Am. Title Ins. Co.*, 668 F. Supp. 2d 282, 295 (D. Mass. 2009) (finding that, “[e]specially given the lack of a viable Chapter 93A claim,” there was no entitlement and thus no unjust enrichment claim).

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<sup>18</sup> To the extent Y-Trap claims that Dr. Bedi’s earlier work is such a benefit, (1) **Y-Trap**, the plaintiff, did not convey it; and (2) Dr. Bedi’s work is public in the published patent applications—there is nothing to convey.

**C. Y-Trap Fails to Plead the Elements of Civil Conspiracy (Count VI).**

Massachusetts courts recognize two theories of civil conspiracy: (1) a theory based on conspiracy to commit a tort and (2) a theory based on a unique coercive effect caused by two parties conspiring together against a third. *Tracey v. Champeon*, 79 N.E.3d 1111, 2017 WL 633778, \* 3 (Mass. App. Ct. 2017). Here, Y-Trap’s claim fails under both theories.

**1. Y-Trap Fails to Plead Civil Conspiracy Based on a Unique Coercive Effect.**

Under this theory, “the plaintiff must allege and prove that by mere force of numbers acting in unison the defendants exercised some peculiar power of coercion of the plaintiff which any individual standing in a like relation to the plaintiff would not have had.” *Gill v. Cohen ± Assocs. LCC*, 2014 WL 6387366, at \*2 (D. Mass. Nov. 14, 2014), *aff’d* No. 15-1075 (1st Cir. Sept. 28, 2015). It is not clear that Y-Trap even intends to avail itself of this theory—the civil conspiracy section of its Complaint makes no references to coercion. (*See* Compl. ¶¶ 143-47.) Nevertheless, Y-Trap does not allege facts to support any peculiar power of coercion placed on Y-Trap by Bicara and Biocon working together in any event. The Complaint does not even say *how* Bicara and Biocon could have “coerced” Y-Trap. The standalone theory of civil conspiracy is not pled.

**2. Y-Trap Fails to Plead Civil Conspiracy Based on a Tort.**

To the extent Y-Trap’s claim against Bicara for civil conspiracy is based in tort, it fails. To plead civil conspiracy based on a tort, a plaintiff must allege “(1) a common design or agreement . . . between two or more persons to do a wrongful act and (2) proof of some tortious act in furtherance of the agreement.” *Mullane v. Breaking Media, Inc.*, 433 F. Supp. 3d 102, 115 (D. Mass. 2020), *aff’d*, 2021 WL 3027150 (1st Cir. Feb. 26, 2021). Here, Y-Trap does not allege (1) any common design or agreement to do a wrongful act or (2) a predicate tortious act.

First, the “conspiracy,” as alleged, is limited to Biocon’s efforts to prosecute the Biocon

Patents. But at the time Biocon and Bicara undertook the alleged “conspiracy,” according to the Complaint, Bicara was a wholly-owned subsidiary of Biocon. Thus, no conspiracy was possible by virtue of the intra-corporate conspiracy doctrine, which “generally forecloses the existence of a conspiracy among a single entity because that entity cannot conspire with itself.” *BlueRadios, Inc. v. Hamilton, Brook, Smith & Reynolds, P.C.*, 2022 WL 138642, at \*9 (D. Mass. Jan. 14, 2022) (quoting *Platten v. HG Bermuda Exempted Ltd.*, 437 F.3d 118, 131 (1st Cir. 2006)). Y-Trap’s conspiracy allegations rest on Biocon’s prosecution of the Biocon IP and Bicara’s license to the Biocon IP. But all of the pertinent facts alleged in the Complaint related to prosecution and use of the Biocon Patents took place before Bicara was spun off from Biocon. (Compl. ¶¶ 72–74.) As such, Biocon and Bicara operated as a “single entity” that could not have conspired with itself. *See BlueRadios*, 2022 WL 138642, at \*9.

Second, Y-Trap fails to plead any predicate tort. Y-Trap alleges that Bicara and Biocon committed a conspiracy against Y-Trap to weaken the Bedi IP, develop and commercialize technologies that compete with Y-Trap, and increase their market share. (Compl. ¶ 145.) None of these alleged actions amount to a tort, and Y-Trap does not attempt plead one. *Mass. ex rel. Powell v. Holmes*, 546 F. Supp. 3d 58, 81 (D. Mass. 2021) (dismissing civil conspiracy claim where “the complaint fails to allege the existence of an underlying tort”). To the extent a Chapter 93A claim could count as a predicate tort, Y-Trap’s 93A claim fails for the reasons discussed *supra* at section II(A). *Cf. Malden Transportation, Inc. v. Uber Techs., Inc.*, 404 F. Supp. 3d 404, 426 (D. Mass. 2019) (“Because plaintiffs have failed to prove their Chapter 93A claim, and subsequently their claim for common law unfair competition, they have failed to prove an underlying tort. Thus, their claim of aiding and abetting fails as matter of law.”), *aff’d sub nom. Anoush Cab, Inc. v. Uber Techs., Inc.*, 8 F.4th 1 (1st Cir. 2021). Therefore, Y-Trap’s claim for

civil conspiracy should be dismissed.

### III. Federal Law Also Preempts Any Potential State Law Claim Against Bicara.

At their core, Y-Trap's claims amount to a patent infringement claim in disguise. Y-Trap alleges that the Bedi IP patents cover ficerafusp alfa (or, alternatively, that Dr. Bedi is the rightful inventor of the Biocon Patents, and thus, they are licensed to Y-Trap), and so Bicara should not be pursuing ficerafusp alfa without Y-Trap's say-so. (Compl. ¶¶ 54, 89.) That is nothing more than a patent infringement claim.

Notably, as alleged in the Complaint, Bicara's actions are **only** wrongful if Y-Trap holds a license to the patents covering ficerafusp alfa. And, as alleged in the Complaint, Bicara's wrongful actions include **only**: (1) developing ficerafusp alfa; (2) taking a legal license to duly issued patents from the patent's current assignee; and (3) raising money to support said development. Y-Trap alleges **no other actions** by Bicara that could amount to (1) "an unfair or deceptive act or practice" under Chapter 93A; (2) "circumstances [that] would be inequitable," *Shields Health Care Grp.*, 2024 WL 939219, at \*7 (requirement for unjust enrichment); or (3) "a wrongful act" *Mullane*, 433 F. Supp. 3d at 115 (requirement for civil conspiracy). Y-Trap's claims here are solely related to patent rights, and, as such, are pre-empted.

Y-Trap cannot seek through state law claims what should otherwise be adjudicated by the patent statutes. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989) ("[T]he states may not offer patent-like protection to intellectual creations which would otherwise remain unprotected as a matter of federal law."). "Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964).

There is no secret as to why Y-Trap seeks to shoehorn its patent claims into state law



claims. Put aside for a moment the weakness, lack of detail, and implausible nature of Y-Trap’s inventorship claims or implicit contention that Dr. Bedi is somehow the sole inventor for an entire class of compounds that have been under continual development by separate pharmaceutical companies for more than a decade. Y-Trap’s Complaint avoids the patent laws because every one of Bicara’s actions related to the development of ficerafusp alfa are expressly protected under the safe harbor in 35 U.S.C. § 271(e)(1), which states that it *cannot* be patent infringement “to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” As alleged in the Complaint, that is *all* Bicara has done. (Compl. ¶¶ 7, 21.) Accordingly, Bicara’s actions at issue in this case are expressly *permitted* by federal law.

Thus, not only is Y-Trap trying to circumvent federal law by bringing a patent infringement claim in disguise, Y-Trap here brings claims for conduct expressly allowed under the safe harbor. Y-Trap’s suit against Bicara is an attempt to circumvent federal law and seek damages for expressly legal conduct. *See Bonito Boats*, 489 U.S. at 156. That attempt should be rejected.

### **CONCLUSION**

Bicara respectfully request that the Court dismiss all claims against Bicara.

Dated: January 10, 2025

Respectfully submitted,

BICARA THERAPEUTICS, INC.

By its attorneys,

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### **CERTIFICATE OF SERVICE**

I hereby certify that the foregoing document was filed using the Court's CM/ECF system and will be served upon all counsel of record as indicated in the Notice of Electronic Filing (NEF) on January 10, 2025.

/s/ Daryl L. Wiesen

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